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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,510	09/29/2005	Karoly Tihanyi	23394	6075

535 7590 08/20/2008

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EXAMINER	
ROGERS, JUNE MARIE	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
08/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,510	TIHANYI ET AL.	
	Examiner	Art Unit	
	JUNE ROGERS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 6-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 6-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed April 25, 2008, have been fully considered and are deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer et al. USP 5,840,731.

Mayer et al. teaches compositions comprising an analgesic, a NMDA antagonist such as dextromethorphan and a muscle relaxant (col. 2, lines 30-34) that are useful for

[1] *Bose, K (1999) "The efficacy and safety of eperisone in patient with cervical spondylosis: results of a randomized, double-blind, placebo –controlled trial. Methods Find Exp. Clin. April; 21 (3) 209-13.*
[2] *Weinbroum A. (2000) "The Role dextromethophan in pain control" Can J Anesth 47:6 pp 585-596.*

treating pain states. Mayer et al. teaches the NMDA antagonist enhances the efficacy of the composition by either a reduction in the amount of analgesic(s) in a dosage unit with out a reduction in the level of pain relief or an increase in the level of pain relief without an increase in the amount of analgesic(s) (col. 2, lines 60-65).

Mayer et al. teaches that the NMDA antagonist amounts can vary between 10 to 100mg per unit dose (col. 4, lines 64-65).

Mayer et al. teaches all modes administration including oral (col. 5, line 1) that when in the form of tablets or capsules contain inert solid diluent (col. 5, lines 7-10).

Mayer et al. discloses several composition comprising muscle relaxants and dextromethophan (col. 7, examples 23-25).

Mayer et al. differs insofar as it discloses the muscle relaxant(s) to be baclofen, carisoprodol, chlorzoxazone, cyclobenzaprine, methocarbamol, orphrenadine and their salts. However, generally it is prima facie obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended purpose. See Sinclair and Carroll Co. v. Interchemical Corp., 325 US 327, 65 YSPQ 297 (1945). See also *In re* Leshin 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Accordingly, in this instance it would have been obvious to have used toleperisone or eperisone as an analgesic[1] and/or a muscle relaxant (see Applicant's disclosure page 1, first paragraph and page 7, second paragraph) since these compounds are recognized to be suitable for those intended purposes.

Alternatively, to the reasoning above, dextromethorphan is known to treat pain[2] therefore, it would have been obvious to incorporate dextromethorphan and tolperisone

[1] *Bose, K (1999) "The efficacy and safety of eperisone in patient with cervical spondylosis: results of a randomized, double-blind, placebo –controlled trial. Methods Find Exp. Clin. April; 21 (3) 209-13.*
[2] *Weinbroum A. (2000) "The Role dextromethophan in pain control" Can J Anesth 47:6 pp 585-596.*

and/or eperison in a composition to treat pain and spasticity, since spasticity is known to be painful muscle spasms and therefore treats pain (see Applicant's disclosure page 1, first paragraph and page 7, second paragraph)

As to the claims 16 and 17, per Applicant's own admission, tolpersion and eperisone are used to treat spasticity (see Applicant's disclosure page 1, first paragraph and page 7, second paragraph) and therefore it would be obvious to used them in such a method.

As to the amounts recited amounts of drug, the determination of dosage is clearly within the abilities of one skilled in the since both tolperisone and eperisone are known compounds, one skilled in the art would be able to discern an appropriate dosages.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

[1] *Bose, K (1999) "The efficacy and safety of eperisone in patient with cervical spondylosis: results of a randomized, double-blind, placebo –controlled trial. Methods Find Exp. Clin. April; 21 (3) 209-13.*
[2] *Weinbroum A. (2000) "The Role dextromethophan in pain control" Can J Anesth 47:6 pp 585-596.*

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JUNE ROGERS whose telephone number is (571)270-3497. The examiner can normally be reached on M-F 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Juné M. Rogers

/Frederick Krass/

[1] *Bose, K (1999) "The efficacy and safety of eperisone in patient with cervical spondylosis: results of a randomized, double-blind, placebo –controlled trial. Methods Find Exp. Clin. April; 21 (3) 209-13.*
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Supervisory Patent Examiner, Art Unit 1612

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